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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,679	08/18/2003	Xavier Paliard	PP01612.009 (2300-1612.10	4593

27476 7590 05/29/2007

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
05/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/643,679	PALIARD ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-5,8,23-33,37-40,42,45 and 46* is/are pending in the application.

4a) Of the above claim(s) *23-33 and 37-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5 and 8* is/are rejected.

7)☒ Claim(s) *3,4,45 and 46* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/16/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 3-5, 8, 23-33, 37-40, 42, 45-46 are pending.

Response to Amendment

This is a response to the amendment filed on 02/22/2007. Claims 3, 4, 5, 8 and 23 have been amended. Claims 1-2, 6-7, 9-22 34-36, 41 and 43-44 were canceled. Claims 23-33, 37-40, 42 were withdrawn from the consideration. Claims 3-5, 8 and 45-46 are considered before the examiner.

Information Disclosure Statement

The information disclosure statement filed on April 16, 2007, 2007 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. In particular, one of the reference WO 96/38474 does not contain the eligible copy of the entire document expect an Abstract. It has been placed in the application file, but the information referred to the entire document therein has not been considered.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 5 is still rejected under 35 U.S.C. 102(b) as being anticipated by Houghton et al. (1) (WO 91/15771A1) or under 102(e) as being anticipated by Houghton et al. (2) (US patent No. 5, 683,864A) on the same ground as stated in the previous office action.

3. Applicants traverse the rejection and submit that none of Houghton et al. references teach the composition for eliciting an antibody or T cell response. None of the reference describes a composition comprising an adjuvant that activates HCV-specific T cells.

4. Applicants' argument has been fully considered; however, it is not persuasive.

5. Firstly, the applicant's argument that the references fail to show certain feature of applicant's invention, i.e. the composition comprising "an adjuvant" is not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

6. Secondly, the claimed product has same structure, the biological activity own by the structurally same product is inherent same. See In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977) [PTO can require an applicant to establish that a prior art product does not necessarily possess the characteristics of the claimed product when the prior art and claimed products are identical or substantially identical. The biological activity cited in the rejected claims is inherently anticipated by the structurally same product disclosed by the prior art. While "indirect comparisons, based on established scientific principles, can validly be applied to distinguish a claimed chemical process or product from that disclosed in the prior art," In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 432 (CCPA 1977), the comparisons must be scientifically valid. Applicants need to provide the scientific evident that the HCV polynucleotide construct that encoding the HCV NS3, NS4, NS5a, NS5b and core taught by Houghton et al. is structurally so different from the clamed one and it does not contain the T cell epitope (s). Patent owner's burden under the circumstances presented herein was described in In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-434 (CCPA 1977) as follows: Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. . . . Whether the rejection is based on `inherency' under 35 U.S.C. § 102, on `prima facie obviousness' under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products [footnote omitted].

Claim Rejections - 35 USC § 102 (e)

7. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

8. Applicant's arguments, see page 8 of the response, filed on Feb. 22, 2007, with respect to Fields' et al. failing to teach the HCV NS5b in their mosaic polypeptide, have been fully considered and are persuasive. The rejection of claims 5 and 8 has been withdrawn.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claim 5 is still provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 45 of copending Application No. 10,612,884.

11. Applicants admit that the conflict claim in the copending application is the species of the generically claimed subject matter in the current claim 5. Applicants do not object the rejection and indicate that the issue will be holed in the abeyance until there is an indication of allowable subject matter in either application. Therefore, the rejection is still maintained.

Upon reconsidering the pending claims, a new ground rejection has been made.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 5 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cho et al. (Vaccine 1999, Vol. 17, pp. 1136-1144) and Lagging et al. (J. Virol. 1995, Vol. 69, No. 9, pp. 5859-5863) or Geissler et al. (J. Immunol. 1997, Vol. 159, pp. 5107-5113).

14. The claimed invention is directed an immunogenic composition comprising a fusion protein consisting of HCV core, NS3-NS5ab, and pharmaceutical expectable excipient as well as an adjuvant.

15. Cho et al. disclose a plasmid DNA that encodes the non-structural polyprotein of HCV comprising NS3, NS4 and NS5 (pTV-NS345). Because the NS5 contains amino acid residues from 1019 to 3010 (See Fig. 1 on page 1139) it inherently comprises NS5a and NS5b. The plasmids are constructed with or without a cytokine of GM-CSF (pTV-NS345/GMCSF, see fig. 1 on page 1139). The three kinds of immunogenic compositions include one formulation comprising two DNA expression vectors encoding NS345 (pTV-NS345) and GM-CSF (pTV-GMCS) separately; one formulation comprising a bicistronic DNA expression vector encoding pTV-NS345/GMCSF, and one formulation comprising pTV-NS345 along. They are all injected into different groups of animals respectively to induce both humoral and T cell specific immune responses against each individual of non-structural proteins including NS3, NS4, NS5a and NS5b with or without adjuvant. T cell specific immune responses specific in each of the NS3, NS4 and NS5 antigens are significantly enhanced with co-expression of GM-CSF (See Table 2 on page 1140).

16. While Cho et al. do not teach to use HCV core, HCV core antigen has been well described to contain both T Cell and B cell immunological epitopes that are able to induce significant T cell (CTL and cytokine) and B cell humoral responses as evidenced by Geissler et

al. (Figs. 1-4) and Lagging et al. (See Figs. 1-4 and Table 1). They have tested identified and several epitopes of HCV core antigen epitopes, they concluded that HCV core is a candidate antigen for developing the genetic vaccine to control the HCV infection (See Abstracts).

17. Therefore, it would have been obvious for any person skill in the art to be motivated for making an immunogenic composition with both HCV structural core and non-structural NS345 antigens for inducing an optimal significant immune responses against each of the HCV replication related antigens optionally with n adjuvant since all of these HCV antigens proteins encode different structural and non-structural proteins are required for the HCV replications. Especially, each of the non-structural proteins encodes different proteases and RNA-dependent replication related enzymes, such RDRP, and each of them has been approved to contain T cell and/or B cell epitopes and is able to induce an significant immune response.

18. Absence unexpected result, the claimed invention as a whole is prima facie obvious absence unexpected results.

Conclusion

Claims 3-4 and 45-46 are allowable if they are writen as independent form.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bao Qun Li May 22, 2007

BAOQUN LI, MD
PATENT EXAMINER